

CLAIMS

- 1           1.       A therapeutic delivery system for a host comprising:  
2                   a therapeutic agent; and  
3                   a sacromastigophoric organism containing said therapeutic agent and a  
4       recombinant lytic factor.
  
- 1           2.       The system of claim 1 wherein said therapeutic agent is selected  
2       from the group consisting of:  
3                   a gene, an artificial chromosome, magnetic species, radioactive species,  
4       vitamins, nanocrystals, drugs, and prodrugs.
  
- 1           3.       The system of claim 2 wherein said therapeutic agent is a gene  
2       selected from the group consisting of: a native organism gene, a host gene, a  
3       pathogen gene, a polymorph of a host gene, a polymorph of a pathogen gene, a  
4       virus, and a provirus.
  
- 1           4.       The system of claim 1 wherein the said organism is selected  
2       from the group consisting of Trypanosoma, Plasmodium, Amoeba, Giardia,  
3       Entamoeba, and Leishmania.
  
- 1           5.       The system of claim 1 wherein said lytic factor is selected from  
2       the group consisting of: Hpr, trialysin, Bad and Bax.

1           6.     The system of claim 5 wherein said trypanosome is  
2     *Trypanosoma brucei*.

1           7.     The system of claim 1 wherein said recombinant lytic factor is  
2     upregulated by a promoter responsive to an induction species exogenous to  
3     both said organism and said host.

1           8.     The system of claim 7 wherein said induction species is an  
2     antibiotic.

1           9.     The system of claim 1 further comprising a gene encoding a  
2     small interfering RNA related to said therapeutic agent.

1           10.    The system of claim 1 wherein said therapeutic agent is a  
2     diagnostic marker.

1           11.    A therapeutic delivery system for a host comprising:  
2           a trypanosome organism containing a recombinant lytic factor  
3     upregulated by a promoter responsive to an induction species exogenous to  
4     both said organism and said host.

1           12.    The system of claim 11 further comprising an expression  
2     cassette having a translatable gene coding for a polypeptide.

1           13.    The system of claim 11 wherein said trypanosome is  
2    *Trypanosoma brucei*.

1           14.    The system of claim 12 wherein said gene codes green  
2    fluorescent protein.

1           15.    The system of claim 12 wherein said expression cassette further  
2    comprises a plurality of translatable genes.

1           16.    A process for producing a sacromastigophoric organism for  
2    delivery of a therapeutic agent comprising the steps of:

3                culturing sacromastigophoric organisms that have been transfected with  
4    an expression cassette induced by a first exogenous species, the cassette  
5    comprising:

6                a first construct having a first promoter controlling expression of a lytic  
7    protein.

1           17.    The process of claim 16 wherein said organism is selected from  
2    the group consisting of:

3                Trypanosoma, Plasmodium, Amoeba, Giardia, Entamoeba, and  
4    Leishmania.

1           18.    The process of claim 16 wherein said organism is a  
2    Trypanosoma.

1           19.    The process of claim 18 wherein said organism is *Trypanosoma*  
2    *brucei*.

1           20.    The process of claim 16 further comprising a second construct  
2    encoding genes comprising a second promoter, a polymerase termination  
3    sequence, and a preselected gene.

1           21.    The process of claim 20 wherein said second construct further  
2    comprises a ribosome binding site and a poly A tail.

1           22.    The process of claim 20 further comprising a gene conferring  
2    resistance to a second exogenous species.

1           23.    The process of claim 16 wherein said first promoter is induced  
2    by said exogenous species.

1           24.    The process of claim 16 wherein said first exogenous species is  
2    an antibiotic.

1           25.    The process of claim 16 further comprising the step of  
2   packaging a non-nucleic acid therapeutic agent in said organism.

1           26.    A process for producing a sacromastigophoric organism for  
2   delivery of a therapeutic agent comprising the steps of:

3                culturing trypanosome organisms that have been transfected with an  
4   expression cassette induced by a first exogenous species, the cassette  
5   comprising:

6                a first construct having a promoter induced by said first exogenous  
7   species controlling expression of haptoglobin related protein.

1           27.    The process of claim 26 further comprising a second construct  
2   encoding genes comprising a second promoter, a polymerase termination  
3   sequence, and a preselected gene.

1           28.    The process of claim 27 wherein said second construct further  
2   comprises a ribosome binding site and a poly A tail.

1           29.    The process of claim 27 further comprising a gene conferring  
2   resistance to a second exogenous species.

1           30.    The process of claim 26 wherein said first exogenous species is  
2   an antibiotic.

1           31.    The process of claim 22 wherein said second exogenous species  
2    is an antibiotic effective against a wild trypanosome.

1           32.    A method of treating or preventing a disease in a host  
2    comprising the steps of:

3               administering to said host a therapeutic amount of a sacromastigophoric  
4    organism that has been transfected with an expression cassette induced by an  
5    exogenous species signal, said cassette comprising a first construct having a  
6    promoter controlling expression of lytic protein;

7               allowing sufficient time for said organism to infect said host; and

8               administering said exogenous species to induce lysis of said organism.

1           33.    The method of claim 32 wherein said organism is selected from  
2    the group consisting of:

3               Trypanosoma, Plasmodium, Amoeba, Giardia, Entamoeba, and  
4    Leishmania.

1           34.    The method of claim 32 wherein said organism is *Trypanosoma*  
2    *brucei*.

1           35.    The method of claim 32 wherein said exogenous species is an  
2    antibiotic.

1           36. The method of claim 32 further comprising the step of  
2           introducing into said organism a second construct encoding genes comprising:  
3           a second promoter, a polymerase termination sequence, integrase, and a  
4           preselected gene.

1           37. The method of claim 36 wherein said preselected gene encodes  
2           a host gene, a pathogen gene, a polymorph of a host gene, a polymorph of a  
3           pathogen gene, a virus, and a provirus.

1           38. The method of claim 32 further comprising the step of  
2           packaging a non-nucleic acid therapeutic agent into said organism prior to  
3           administering said organism to said host.

1           39. The method of claim 38 wherein said non-nucleic acid  
2           therapeutic agent is selected from a group consisting of: magnetic species,  
3           radioactive species, vitamins, nanocrystals, drugs, and prodrugs.

1           40. The use of an intracellular parasite containing a recombinant  
2           exogenous species induced lytic factor to deliver a therapeutic agent to a host.

1           41. An organism obtainable by the process as claimed in claim 16.

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- 1 42. A commercial package comprising a therapeutic agent delivery system
- 2 according to claim 1 as an active ingredient with instructions for the use thereof
- 3 as a therapeutic.